## REMARKS

The Office Action dated May 25, 2005 has been carefully reviewed. Claims 13 and 30 are pending in the application. Claims 1-12 and 14-29 have been withdrawn without prejudice to the right to file one or more divisional applications directed thereto. Applicant requests reconsideration of the rejections and allowance of the claims on the basis of the following remarks.

35 USC 102(b) Rejection

Claim 13 has been rejected under 35 USC 102(b) as being anticipated by Power et al., "Genetic characterization of pilin glycosylation in *Neisseria meningitidis*," Microbiology (April 2000), Vol. 146 (Pt 4), pp 967-979. According to the Office Action, the Power et al. reference ("Power") discloses a composition comprising a glycosylated pilin, which inherently contains an O antigen, and a pharmaceutically acceptable carrier. Applicant respectfully traverses the 35 USC 102(b) rejection with respect to Claim 13.

Claim 13 has been amended to recite that the glycosylated pilin is produced by introducing a vector containing genes encoding an O-antigen of a Gram-negative bacterium, other than *Pseudomonas aeruginosa*, into a strain of *Pseudomonas aeruginosa* containing the *pilO* gene, such that said O-antigen is expressed in said *Pseudomonas aeruginosa* and said pilin is glycosylated with said O-antigen of said Gram-negative bacterium, and isolating said glycosylated pilin. Thus, Claim 13 has been amended from a product claim to a product-by-process claim.

Applicant submits that amended Claim 13 is not anticipated by Power. Power discloses the isolation of glycosylated pilin from *Neisseria meningitidis*. In contrast, amended Claim 13 recites the isolation of glycosylated pilin from *Pseudomonas aeruginosa*. In addition, Power does not disclose the O-antigen. The LPS produced by the organism studied by Power (*Neisseria meningitidis*) does not contain O-antigen. This organism does not produce an O-antigen, and the glycan attached to the pilus of this organism is not O-antigen. Furthermore, Power does not disclose heterologous glycosylation or its application in vaccine design in contrast to the present application.

Based on the foregoing remarks, Applicant submits that amended Claim 13 is patentable over Power, and the 35 USC 102(b) reference is respectfully traversed.

35 USC 102(e) Rejection

Claim 13 has been rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,872,398 to Castric et al. (the "'398 patent"). According to the Office Action, the '398 patent discloses glycosylated pili which are covalently attached to O-antigen repeating units of different strains or species of Gram-negative bacteria in a pharmaceutically acceptable carrier. Applicant respectfully traverses the 35 USC 102(e) rejection with respect to Claim 13.

Claim 13 has been amended to recite that the glycosylated pilin is produced by introducing a vector containing genes encoding an O-antigen of a Gram-negative bacterium, other than *Pseudomonas aeruginosa*, into a strain of *Pseudomonas aeruginosa* containing the *pilO* gene, such that said O-antigen is expressed in said *Pseudomonas aeruginosa* and said pilin is glycosylated with said O-antigen of said Gram-negative bacterium, and isolating said glycosylated pilin. Thus, Claim 13 has been amended from a product claim to a product-by-process claim

Applicant submits that amended Claim 13 is not anticipated by the '398 patent because the '398 patent discloses a different process for producing the glycosylated pilin. In the '398 patent, the vaccine is made by placing the gene for pilin production (*pilA*) and the gene for glycosylation of *P. aeruginosa* pilin (*pilO*) in the pathogen of interest. This requires that the pathogen of interest be able to produce *P. aeruginosa* pilin with the addition of these two genes. A number of pathogens do not produce pili. Many do not produce pili of the type made by *P. aeruginosa*. This means that the majority of pathogens are not compatible with this approach (although this would be a reasonable approach for Pseudomonas and close relatives). This approach has a second drawback in that the large-scale handling of dangerous pathogens is required to insert the genes of interest, but more importantly, to prepare the pili. In the present application, however, the vaccine is made by cloning O-antigen genes from any pathogen that produces an O-antigen (nearly all do), and expressing them in *P. aeruginosa* where these genes will produce the glycan for pilin glycosylation (page 2, paragraph 13). Extensive handling of dangerous pathogens is not required in the

production of the vaccine (page 2, paragraph 13). The value of the present application is that the genes for making the O-antigen of various pathogens can be put into *P. aeruginosa*, with the heterologously glycosylated pili being produced by this organism. Altogether, this lessens the need to handle dangerous pathogens and vastly increases the types of vaccines that can be safely and efficiently made. [*P. aeruginosa* can be handled safely by healthy individuals because it is an opportunistic pathogen and only infects compromised individuals. In addition, this organism has been used for many years in biochemical, physiological, genetic and molecular biological studies of pili (it is considered a model organism) providing a huge amount of background information that can be used in the application of this process.]

Amended Claim 13 is a product-by-process claim that recites a vaccine made according to the unique process described hereinabove. As a result, Applicant submits that amended Claim 13 is patentable over the '398 patent, and the 35 USC 102(e) reference is respectfully traversed

Double Patenting Rejection

Claim 13 has been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-6 of U.S. Patent No. 6,872,398 to Castric et al. (the "'398 patent"). Applicant submits herewith a terminal disclaimer over U.S. Patent No. 6,872,398, which should obviate the double patenting rejection.

New Claim

New dependent Claim 30 has been added to the application. Basis for the language of Claim 30 is located in the specification, e.g., at page 4, paragraph 49.

Summary

In view of the foregoing amendments and remarks, Claims 13 and 30 are believed to be in allowable form. Applicant respectfully requests allowance of the application. In accordance with MPEP 821.04, Applicant also requests rejoinder of the withdrawn process claims corresponding to Groups I and II (Claims 1-12, 14, and 28-29).

In the event that any outstanding matters remain in connection with this application, the Examiner is invited to telephone the undersigned at 412-566-5941.

Respectfully submitted,

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